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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,276	11/02/2001	Spencer W. Beaufore	OPME / 05	8989

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EXAMINER

BOGART, MICHAEL G

ART UNIT PAPER NUMBER

3761

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/000,276

Applicant(s)

BEAUFORE ET AL.

Examiner

Michael G. Bogart

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-19, 21-26, 28, 30, 31 and 98-106 is/are allowed.
- 6) ☒ Claim(s) 5, 11, 13, 32, 34, 42, 50, 54-56, 67, 79, 80, 87, 89-92, 95, 110 and 111 is/are rejected.
- 7) ☒ Claim(s) 4, 6-11, 15, 40, 43, 53, 57-66, 69-78, 81-86, 88, 93, 94, 96, 97 and 107-109 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1, 4-13, 15, 17-19, 21-26, 28, 30-32, 34-38, 40, 42-50, 53-67 and 69-111.

DETAILED ACTION

Withdrawal of Allowability

Prosecution on the merits of this application is reopened on claims 1, 5, 12, 13, 32, 34-37, 42, 50, 54-56, 67, 79, 80, 87, 89-92, 95, 110 and 111 are considered unpatentable for the reasons indicated below.

It is noted that the modifications to the claims made in the Examiner's Amendment dated 12 May 2005 are still in effect.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 50, 56, 67, and 80 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims each have a limitation of a double-duckbill valve having first and second apexes which are perpendicular to each other. The claims have a further limitation that a single slit is formed in only one of the apexes. This limitation is not physically possible with a double-duckbill valve which has intersecting apexes. The single slit crosses over the opposite "slit less" apex at the intersection of the apexes, meaning the slit less apex includes part of a slit which runs across the perpendicular apex.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 34-37, 42, 89-92, 95, 110 and 111 are rejected under 35 U.S.C. § 102(e) as being anticipated by Schmidt (US 2002/0170557 A1).

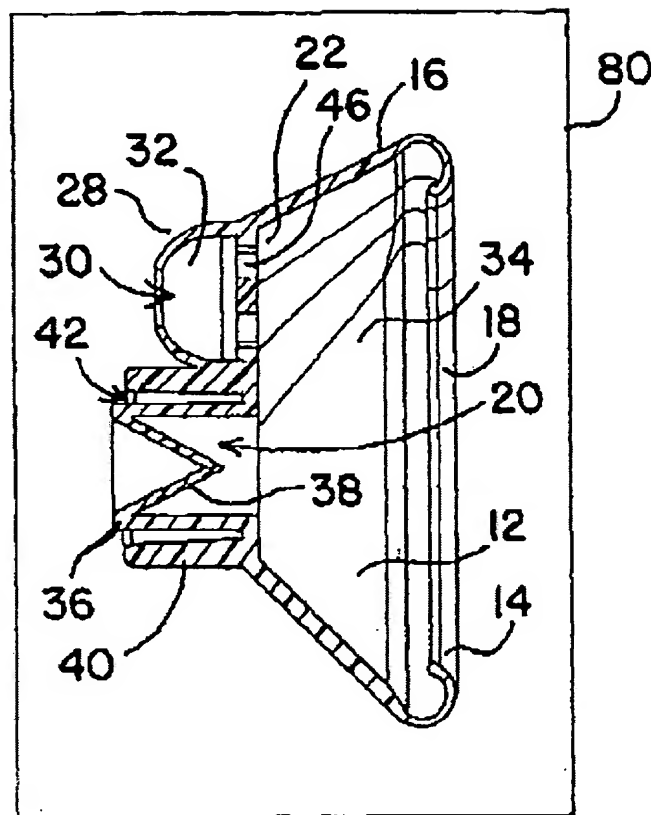
Regarding claims 32, 89 and 90, Schmidt teaches a flow control valve comprising;

a valve member (38) having a normally closed inlet orifice;

a valve housing (40); and

an isolation member (36) extending between said valve housing (40) and said valve member (38) whereby to support said valve member (38) in spaced relationship (42) to said valve housing (40);

said isolation (36) member being a stem (see figure 4, below).



Regarding claim 42, duckbill valves comprise at least one slit.

Regarding claims 35, 91 and 92, Schmidt teaches a tubular stem (36).

Regarding claim 36, Schmidt teaches that the stem (36) is connected to the valve (38) to allow fluid to flow through the stem (36).

Regarding claims 34, 37, 91, 95 and 111, Schmidt teaches that the valve and housing is made from an elastomeric material and hence flexible (§ 0021).

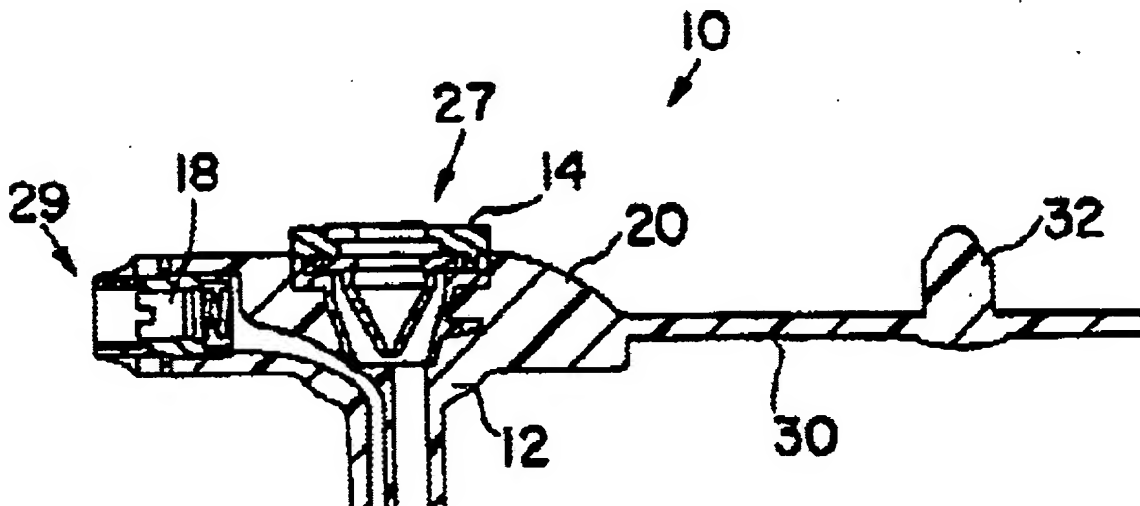
Regarding claim 110, Schmidt teaches a valve member (38) contained within the valve housing (40).

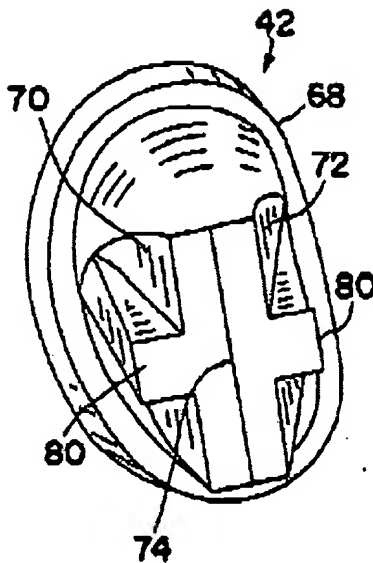
Claims 1, 5, 12, 13, 50, 54, 55, 79, 80 and 87 are rejected under 35 U.S.C. § 102(e) as being anticipated by Willis *et al.* (US 6,767,340 B2).

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Regarding claim 1, Willis *et al.* teach a liquid flow control valve comprising:

- a double-duckbill valve (42) adapted to fluidly communicate with a discharge passageway, said double-duckbill valve (42) having:
 - an inlet orifice (42) operable to control urine flow therethrough;
 - a first duckbill structure having a first pair of inclined walls terminating at a first apex; and
 - a second duckbill structure oriented perpendicular to said first duckbill structure and having a second pair of inclined walls terminating at a second apex;
- said inlet orifice (74) comprising a single slit formed in only one of said first and second apexes (see figures 2 and 8, below).



**FIG. 8**

Willis *et al.* further teach that the slit less apex (80) can be a flared V-shape, which would have inclined walls (col. 4, lines 20-35).

Regarding claims 5 and 12, Willis *et al.* teach a valve housing (40) defined by at least one wall; and

an isolation member (68) extending from said wall to said valve (42), said valve (42) being supported in said valve housing (40) in spaced relationship with said wall (fig. 2).

Regarding claim 13, Willis *et al.* further teach that the stiffening member (80) serves as a crush-limiting member.

Regarding claim 50, Willis *et al.* teach a catheter comprising the above discussed valve (42) and valve housing (40) structure. Claim 50 has no recited structure to distinguish it from the catheters taught by Willis *et al.*

Regarding claims 54, Willis *et al.* teach a valve housing (40) defined by at least one wall; and

an isolation member (68) extending from said wall to said valve (42), said valve (42) being supported in said valve housing (40) in spaced relationship with said wall (fig. 2).

Regarding claim 55, Willis *et al.* further teach that the stiffening member (80) serves as a crush-limiting member.

Regarding claim 79, Willis *et al.* teach a catheter (10) comprising:

a discharge passageway (34);
a liquid flow control valve (42) associated with said discharge passageway;
said flow control valve (42) being a double-duckbill valve (42);
said double-duckbill valve (42) having an inlet orifice (74) operable to control liquid flow therethrough;

a valve housing (40) defined by at least one wall; and
an isolation member (68) extending from said wall to said double-duckbill valve (42), said double-duckbill valve (42) being suspended in said valve housing (40) in spaced relationship with said wall by said isolation member (68)(see figures 2 and 8, below).

Regarding claims 80 and 87, Willis *et al.* teach that the inlet (74) is formed in only one of the apex walls. Willis *et al.* further teach that the stiffening member (80) serves as a crush-limiting member and can be a flared V-shape, which would have inclined walls (col. 4, lines 20-35).

Allowable Subject Matter

Claims 17-19, 21-26, 28, 30, 31 and 98-106 are allowed.

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Claims 4, 6-11, 15, 40, 43, 53, 57-66, 69-78 81-86, 88, 93, 94, 96, 97 and 107-109 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

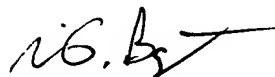
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Larry Schwartz may be reached at phone number (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart
13 June 2005



Larry I. Schwartz
Supervisory Patent Examiner
Group 3700